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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Ventana Medical Systems, Inc. developed Anti-CD3 (Clone UCHT-1) for use on the Ventana ES automated immunohistochemistry system. Ventana's Anti-CD3 (Clone UHCT-1) is substantially equivalent to antibodies detecting cellular elements of lymphocytic origin as reported by Reinherz, E. L., and S. F. Schlossman. The differentiation and function of human T lymphocytes. *Cell.* 1980; Vol 19, pp. 821-827.

Comparative Study

Supporting data for the equivalence statement is shown by the following study. Frozen preparations from normal and pathologic samples were tested using Ventana's Anti-CD3 (Clone UCHT-1). Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic and normal tissues were examined. Slides were processed on the Ventana ES Automated Slide Stainer, prepared for examination, and evaluated by a qualified pathologist for specific staining intensity and background staining.

Results

Staining occurred in the plasma membrane of cells from normal tonsil, thymus and blood. Negative control tissue was all negative. There was no inappropriate staining of the tissues in this study.

Specificity of the antibody was shown with appropriate staining of cells of lymphoid origin and no staining of cells of non-lymphoid origin. In addition, the specificity seen in this study agrees with the data published by Reinherz, E. L., and S. F. Schlossman, 1980.

The sensitivity of this antibody was shown by consistent staining of 8 of 9 T cell lymphomas, and appropriate staining of normal lymphoid tissue. As with any immunohistochemical reagent, the sensitivity is dependent on tissue processing and slide preparation parameters. The negative control which was run with each tissue gave negative results.

Staining intensity was scored on a scale of 0 - 4+. Inter-run reproducibility was determined based on samples of the same tissue on 10 different instrument runs with a mean staining intensity and standard deviation of 4.00 ± 0.00. Intra-run reproducibility was determined based on 10 samples of the same tissue within one run. The mean staining intensity and standard deviation of the ten slides was 4.00 ± 0.00.